

ACID REDUCER ORIGINAL STRENGTH- famotidine tablet
ACID REDUCER MAXIMUM STRENGTH- famotidine tablet
Dr.Reddys Laboratories Inc.

Dr.Reddy's Laboratories Limited

Active ingredient (in each tablet)

Famotidine USP, 10 mg/20 mg

Purpose

Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating, or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **For Famotidine 10 mg:**
- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor
- **For Famotidine 20 mg:**
- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **10 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture and light

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, synthetic red iron oxide (only in 10 mg), talc and titanium dioxide

Questions or comments?

call 1-888-375-3784


Tips For Managing Heartburn**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Principal Display Panel

Famotidine 20 mg

Container Label

HealthCare  Aisle

NDC 43598-960-65

Maximum Strength

Acid Reducer

Famotidine Tablets USP, 20 mg

Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion

65 Tablets

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet) Famotidine USP 20 mg

Purpose Acid reducer Uses ■ relieves heartburn associated with acid indigestion and sour stomach ■ prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings Allergy alert: Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ with other acid reducers. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with light-headedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain ■ kidney disease

Other information

■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20°-25°C (68°-77°F) ■ protect from moisture ■ active ingredients colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, talc and titanium dioxide

Questions? call 1-888-375-3784

DISTRIBUTED BY:

Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540

Made in India

REV 07/20

150081726

LOT

EXP

Principal Display Panel

Famotidine 20 mg Container Carton Label

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Warnings Allergy alert: Do not use if you are allergic to famotidine or other acid reducers. Do not use ■ if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ with other acid reducers. Ask a doctor before use if you have ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with light-headedness, sweating, or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain ■ kidney disease

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days

if pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions ■ adults and children 12 years and over: ■ to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. ■ to prevent symptoms, swallow 1 tablet with a glass of water at any time from 10 to 60 minutes before eating food or drinking beverages that cause heartburn ■ do not use more than 2 tablets in 24 hours ■ children under 12 years: ask a doctor

Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20°-25°C (68°-77°F) ■ protect from moisture

Inactive ingredients colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, talc and titanium dioxide

Questions? call 1-888-375-3784

Tips for Managing Heartburn

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• Do not wear tight-fitting clothing around the stomach

• Do not eat before bedtime

• Raise the head of your bed

• Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolates, caffeine, alcohol and certain fruits and vegetables

• Eat slowly and avoid big meals

• If overweight, lose weight

• Quit smoking

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Maximum Strength Pepcid AC®. Pepcid AC® is a registered trademark of Johnson & Johnson.

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Compare to the active ingredient in Maximum Strength Pepcid AC®

actual size

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Route of Administration	ORAL
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Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)		FAMOTIDINE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	C;118
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-824-18	1 in 1 CARTON	09/01/2020	
1		180 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077367	09/01/2020	

ACID REDUCER MAXIMUM STRENGTH			
famotidine tablet			

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-960(NDC:55111-396)
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)			FAMOTIDINE	20 mg
Inactive Ingredients				
Ingredient Name				Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
STARCH, CORN (UNII: O8232NY3SJ)				
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	L1	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-960-65	1 in 1 CARTON	09/01/2020	
1		65 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-960-32	1 in 1 CARTON	09/01/2020	
2		170 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA077367	09/01/2020	

Labeler - Dr.Reddys Laboratories Inc. (802315887)

Revised: 8/2020

Dr.Reddys Laboratories Inc.